CLINICAL PRACTICE UPDATE

AGA Clinical Practice Update on Role of EUS-Guided Gallbladder Drainage in Acute Cholecystitis: Commentary

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DESCRIPTION: **Endoscopic gallbladder drainage is a feasible and efficacious alternative to percutaneous drainage in the management of acute cholecystitis for high-risk surgical candidates. Endoscopic ultrasound–guided gallbladder drainage and per-oral cholecystoscopy is facilitated by the use of lumen-apposing metal stents. Endoscopic ultrasound–guided gallbladder drainage should be performed by those expert in advanced therapeutic endoscopic ultrasound. Multidisciplinary collaboration between interventional radiology and surgery is paramount in the care of these patients. Choosing the optimal drainage method is dependent on individual patient characteristics.**

METHODS: **This commentary was drawn from a review of the literature to provide practical advice. Because this was not a systematic review, we did not perform any formal rating of the quality of evidence or strength of the presented considerations. This expert commentary was commissioned and approved by the American Gastroenterological Association (AGA) Institute Clinical Practice Updates Committee and the AGA Governing Board to provide timely guidance on a topic of high clinical importance to the AGA membership, and underwent internal peer-review by the Clinical Practice Updates Committee and external peer-review through standard procedures of *Clinical Gastroenterology and Hepatology*.**

Keywords: Acute cholecystitis; EUS; ERCP; per-oral cholecystoscopy; gallbladder drainage.

Acute cholecystitis is a common condition in the United States and cholecystectomy is the definitive treatment.[1] However, patients may be deemed inoperable because of comorbidities. Percutaneous transhepatic gallbladder drainage (PT-GBD) is the most common, nonsurgical method for gallbladder decompression. PT-GBD was first described in the 1970s and its use has been studied extensively.[2–4] However, drain-related complications, including frequent tube changes and discomfort, limit its use long term.[2] Endoscopic treatment via transpapillary gallbladder drainage (ET-GBD) and, more recently, endoscopic ultrasound–guided gallbladder drainage (EUS-GBD) have been developed for endoscopic management of acute cholecystitis in high-risk surgical patients.[2] With the use of lumen-apposing metal stents (LAMS), EUS-GBD is associated with high rates of technical and clinical success and low rates of adverse events.[5] In this clinical practice update, we comment on the role of EUS-GBD (compared with ET-GBD and PT-GBD) in the management of acute cholecystitis, and describe its indications, contraindications, procedural considerations, and associated adverse events.

Evolution of EUS-GBD

PT-GBD has a significant morbidity, ranging from 50% to 75%,[2] and recurrent cholecystitis can occur in up to 15.4% of patients.[3] This led to the evolution of endoscopic gallbladder drainage, which can be achieved by a transpapillary or transmural approach.[2,5] Transpapillary drainage during ET-GBD is performed at endoscopic retrograde cholangiopancreatography (ERCP) by cannulating the cystic duct, allowing placement of a plastic stent. However, obstructing pathology (stone, stricture, or mass) of the cystic duct may result in lower technical and clinical success rates when compared with EUS-GBD (84% vs 98% and 91% vs 97%, respectively).[6] ET-GBD also does not allow for treatment of gallstones, and patients may require stent exchanges.[7]

The transmural EUS-GBD approach involves placing a stent from the duodenum or stomach into

Abbreviations used in this paper: **AGA, American Gastroenterological Association; GB, gallbladder; ERCP, endoscopic retrograde cholangiopancreatography; EUS-GBD, endoscopic ultrasound–guided gallbladder drainage; ET-GBD, endoscopic transpapillary gallbladder drainage; LAMS, lumen-apposing metal stent; PT-GBD, percutaneous transhepatic gallbladder drainage.**

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the gallbladder under EUS guidance. Pigtail plastic stents and biliary self-expandable metal stents were ill-suited for this indication because of their risk of leakage, longer length causing contralateral wall injury or occlusions, and risk of migration owing to a lack of flanges. LAMS have overcome these limitations because they have a short length with large flanges and are available in large diameters (6–20 mm), allowing passage of gallstones or the endoscope as needed for therapeutic cholecystoscopy.[8] There currently are 3 different LAMS designs available in Europe and Asia, but only 1 type commercially available in the United States. Over the past few years, several case-series and comparative trials of EUS-GBD, including a randomized prospective trial with LAMS vs PT-GBD showing its superiority, have been published.[9–15] These outcomes are discussed later. Table 1 summarizes the description, patient selection, and procedural risk of each of the discussed gallbladder drainage modalities.

Indications for EUS-GBD

The following are the suggested indications for EUS-GBD:

- For gallbladder drainage in high-risk surgical risk patients with acute cholecystitis[1];
- Removal of percutaneous cholecystostomy drains in patients who are not candidates for cholecystectomy by allowing internal drainage[11];
- For drainage of malignant biliary obstruction in select patients with failed ERCP and EUS-guided biliary drainage.[16]

Patient Selection

EUS-GBD should be considered in patients who are at high risk for surgery, without evidence of free gallbladder (GB) perforation, and have the ability to tolerate anesthesia and a therapeutic endoscopic procedure. There is a compelling argument for initial consideration of ET-GBD in patients already requiring ERCP for other reasons (choledocholithiasis, suspected cholangitis), or for potential future surgical candidates.[12,17] Furthermore, ET-GBD is particularly useful in patients with coagulopathy, large-volume abdominal ascites, or comorbidities that may preclude optimal percutaneous drain placement or EUS-GBD. An advantage of ET-GBD over EUS-GBD is the preservation of normal anatomy for surgery.[7] Although cholecystectomy with fistula repair after EUS-GBD appears to be safe and feasible in limited data,[18] there is a risk for a postoperative leak. Therefore, before EUS-GBD, discussion with the surgeon is imperative to clarify potential future surgical candidacy and comfort of the surgeon dealing with a transmural stent. A specific indication for EUS-GBD over of

Table 1. Summary of Procedure Description, Patient Selection, and Special Consideration for PT-GBD, ET-GBD, and EUS-GBD

Gallbladder drainage modality	Description	Patient selection	Advantages	Disadvantages
PT-GBD	Ultrasound- (or computed tomography–) guided percutaneous drain placement into the gallbladder	Conventional treatment in patient with acute cholecystitis and with significant medical comorbidities that would make laparoscopic cholecystectomy excessively risky	Widely available	Higher reintervention rate (drain exchanges) Higher risk of recurrent cholecystitis Dyscosmesis
ET-GBD	ERCP with selective cannulation of the cystic duct and transpapillary stent placement	Consider in the following: Patients requiring ERCP for other indications Future cholecystectomy candidates Patient with large-volume ascites Coagulopathy	Can simultaneously address choledocholithiasis and cholangitis Safer in patients with ascites	Lower technical success Lowest clinical success Risk of pancreatitis May need stent changes or replacement if migration occurs
EUS-GBD	EUS-guided placement of a stent from the duodenum or the stomach into the gallbladder	Consider in the following: Patients with in-dwelling, uncovered, metal biliary stent Malignant obstruction of the cystic duct takeoff Large burden of cholelithiasis	Least likely to need reintervention	May require fistula closure if patient undergoes cholecystectomy May become occluded with food Contraindicated in patients with gallbladder perforation

ERCP, endoscopic retrograde cholangiopancreatography; ET-GBD, endoscopic transpapillary gallbladder drainage; EUS-GBD, endoscopic ultrasound guided gallbladder drainage; PT-GBD, percutaneous gallbladder drainage.

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ET-GBD includes an in-dwelling metal biliary stent obstructing the cystic duct takeoff, and patients with a large burden of cholelithiasis or other clinical indications for cholecystoscopy.[7]

Contraindications

EUS-GBD is not advised if there is evidence of gallbladder perforation, biliary peritonitis, large-volume ascites, or significant coagulopathy. Patient intolerance to anesthesia is also a contraindication to all forms of endoscopic GBD. Discussion with the surgical team about potential future surgical candidacy is important to elucidate preference for preservation of normal anatomy, as is achieved with ET-GBD vs EUS-GBD, which would require fistula repair at the time of cholecystectomy.[7,9,19]

Informed Consent

When counseling patients and their families about EUS-GBD, an informed discussion of the risks, benefits, and alternatives is paramount. In the case of using LAMS, the patient should be informed that this, as of now, is an off -label use of this technology. In addition to the standard endoscopic procedural risks, there are specific EUS-GBD–related adverse events including puncture-induced hemorrhage or bile leak with peritonitis, GB perforation, and stent migration.[20] Potential late adverse events include relapsing cholecystitis in the case of stent migration or occlusion. In addition, patients should be informed that future surgery for cholecystectomy may be more difficult or not possible after EUS-GBD.

Technique of EUS-GBD

The 2 approaches of performing EUS-GBD are dependent on whether the LAMS has a cautery-enhanced tip or not. The non–cautery-enhanced method involves puncturing the gallbladder with a fine-needle aspiration needle (typically 19 gauge), followed by guidewire insertion, track dilation, and stent placement under fluoroscopic guidance. The second technique (direct method) requires a cautery-enhanced LAMS to enter the gallbladder directly and deploy the stent through the duodenal or gastric wall without the need for a guidewire or device exchange. Under endosonographic guidance, the gallbladder flange then is deployed, pulled back snugly, followed by the deployment of the duodenal/gastric flange under EUS or endoscopic visualization[21] (Figures 1 and 2). The advantage with the direct method is that the entire procedure could be performed solely under EUS guidance without the need for fluoroscopy unless a salvage maneuver may be needed. The LAMS available in the United States are fully covered and loaded onto a 10.5F catheter-based delivery system that requires a 3.7-mm accessory channel on a therapeutic EUS scope. The typical sizes of LAMS used for EUS gallbladder drainage include having a saddle length of 10 and 15 mm, and inner diameters of 10, 15, and 20 mm, with bilateral anchor flanges of 21, 24, and 29 mm (Axios; Boston Scientific, Natick, MA). For safe deployment, the distance between the enteral puncture site and gallbladder lumen should be less than 10 mm. In patients

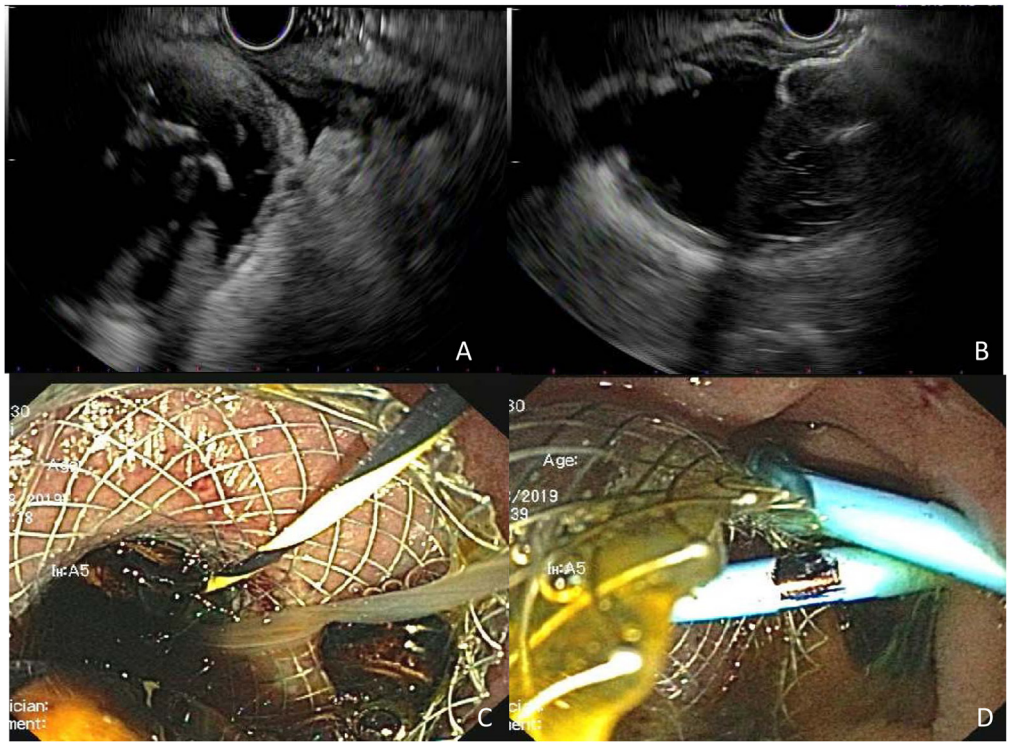


Figure 1. Endoscopic and endosonographic images of endoscopic ultrasound–guided gallbladder drainage. (*A*) Gallbladder with stones and thick wall. (*B*) Distal flange of lumen-apposing metal stents (LAMS) inside the gallbladder. (*C*) Proximal flange of LAMS in the duodenal bulb with gallstones visible. (*D*) Double pigtail stents through the LAMS.

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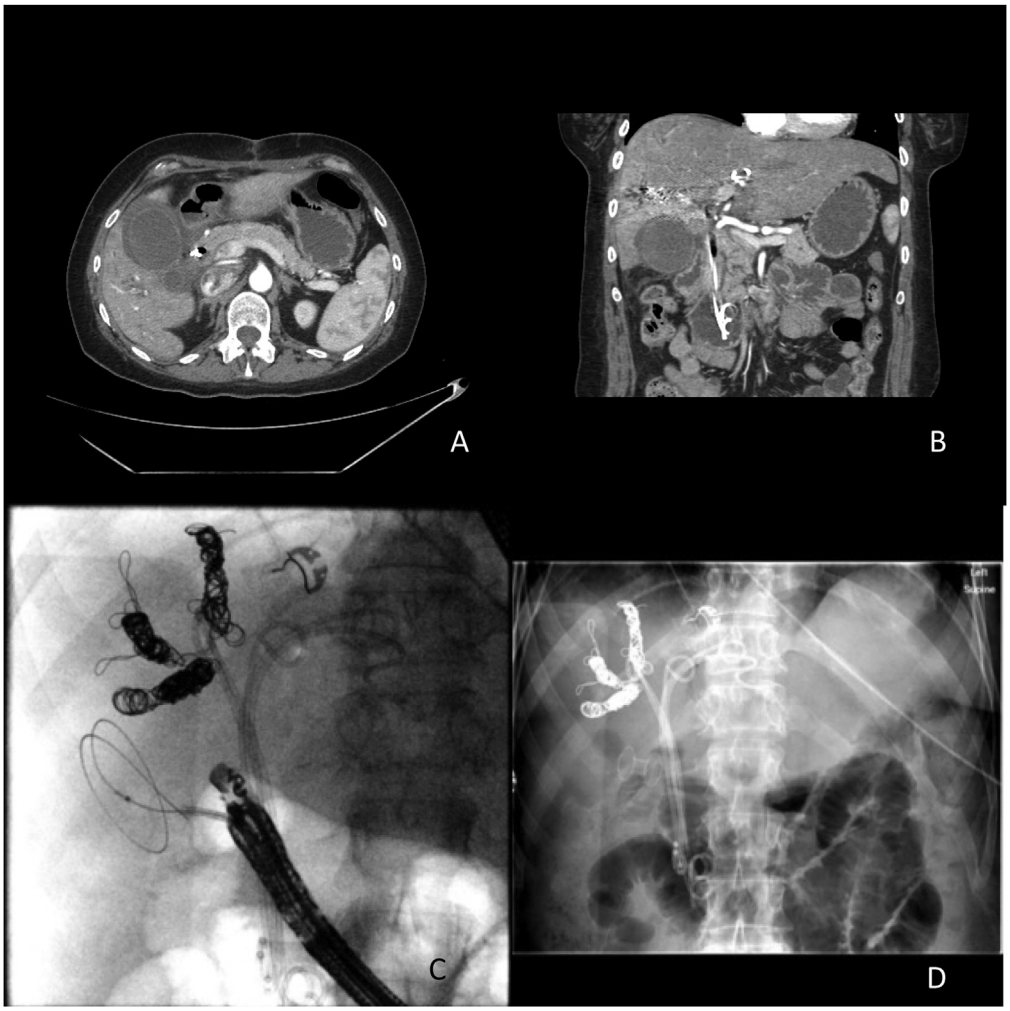


Figure 2. Fluoroscopic images of endoscopic ultrasound–guided gallbladder drainage. (*A* and *B*) computed tomography scan showing acute cholecystitis. Fluoroscopic image of distal flange deployment inside the gallbladder (*C*). Fluoroscopic image of complete lumen-apposing metal stents deployment (*D*).

with gallbladders that are fibrotic and contracted, with existing percutaneous drains, or in difficult endoscope positions, we prefer an over-the-wire technique that maintains access in case of stent misdeployment. No significant differences in adverse events have been reported between drainage from the stomach or duodenum,[22] but our preference is for EUS-GBD from the duodenum because food can cause occlusion more easily when LAMS are placed in the prepyloric antrum. Furthermore, in our experience, there is a higher risk of inward stent migration in the gastric antrum owing to gastric contraction forces.[23] However, if there is a complication with the procedure or the patient undergoes subsequent cholecystectomy and the drainage site must be closed, it is easier for the surgeons to access the distal stomach than the duodenum. Therefore, multiple factors are considered but the most important thing for the endoscopist is to find the area where there is the closest apposition of the gallbladder to the gastrointestinal tract wall. Placement of a double pigtail plastic biliary stent across the LAMS, although not universally performed, is routine in our practice to potentially mitigate these potential complications including bleeding, stent obstruction, and contralateral wall injury from the LAMS.[7]

Outcomes of EUS-GBD

Adverse Events

Postprocedure complications are of a wide range but occur infrequently. In a meta-analysis, the reported complications included stent dislodgement, stent blockage, leak, peritonitis, pneumoperitoneum, abdominal abscess, and recurrent cholecystitis.[4] These morbidities were noted in 20.4% of patients undergoing EUS-GBD. The overall mortality rate was 3.9%, which predominantly was owing to ongoing sepsis. In a recent systematic review, EUS-GBD had the lowest risk of recurrent cholecystitis compared with other modalities (relative risk for EUS-GBD vs PT-GBD vs ET-GBD, 1.089 vs 2.02 vs 2.891), whereas ET-GBD was associated with the lowest rates of mortality (relative risk for EUS-GBD vs PT-GBD vs ET-GBD, 2.62 vs 2.09 vs 1.29).[24]

Endoscopic Vs Percutaneous GBD

Despite limitations of drain-related dyscosmesis and maintenance issues, there is an extensive body of

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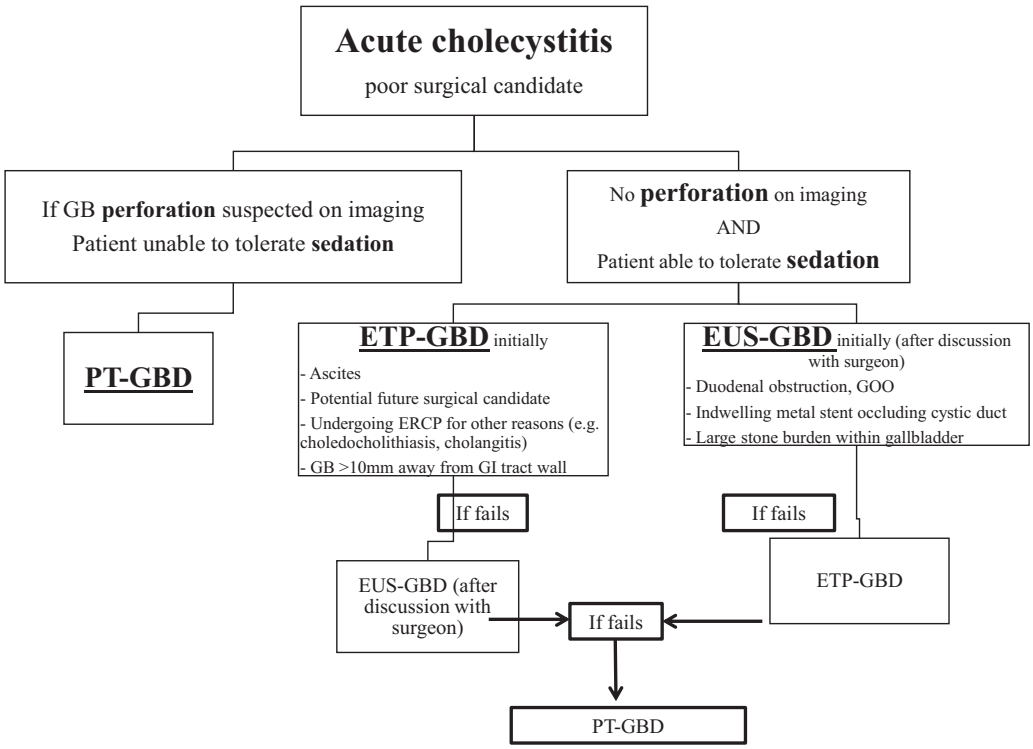


Figure 3. Approach to cholecystitis in high surgical risk patients algorithm.

literature to support the use of PT-GBD, particularly because of the ubiquity of procedural expertise. Furthermore, until recently, there was a paucity of compelling evidence to support endoscopic alternatives. EUS-GBD boasts very high technical and clinical success rates ranging from 90% to 98.7% and 89% to 98.4%, respectively.[9,11,13,15] Adverse events occur in 4.8% to 22% of cases and include bleeding, recurrent cholecystitis, stent migration, and occlusion.[7] Given this nonsurgical patient population tends to have multiple comorbidities, care should be taken to minimize complications.

Five studies including 488 patients to date have compared EUS-GBD with PT-GBD, including a recent prospective randomized controlled study.[9,12–14,25] Four studies used LAMS and 1 study used fully covered self-expandable metal stents. Despite comparable technical and clinical success rates,[12–15,25] patients treated with PT-GBD seem to experience longer hospital stays, greater time to clinical resolution, and higher procedure reintervention rates in comparative studies.[13–15] Recurrent acute cholecystitis also was more frequent in the PT-GBD group than in the EUS-GBD group (1 of 39 [2.6%] vs 8 of 40 [20%]; $P = .029$).[14]

Multicenter data also have shown that PT-GBD is associated with higher postprocedure pain scores with a trend toward higher adverse events at 30 days[13,25] and at 1 year[14] when compared with EUS-GBD. Lower postprocedure pain scores after EUS-GBD may account for the shorter postintervention hospital stay. Readmission rates for the PT-GBD group were owing to drain-related leaks, obstruction, or dislodgement.[9,13,15]

Transpapillary Vs EUS-Guided GBD

More recently, data have emerged that suggest the superiority of EUS-GBD over ET-GBD as a definitive treatment in the high-surgical-risk patient. One recent multicenter study comparing ET vs EUS vs PT-GBD found significantly lower technical and clinical success rates in the transpapillary drainage arm,[26] which was similar to a meta-analysis from 2020.[27] In a single US-based series comparing ET-GBD with EUS-GBD, clinical success was higher in the EUS arm with a trend toward higher technical success as well.[6] Cystic duct occlusion by tumors, stones, or uncovered metal biliary stents are the primary reason for technical failures with ET-GBD. Lower rates of recurrent cholecystitis after EUS drainage also have been reported.[26] Figure 3 shows our approach to management of cholecystitis in high-risk surgical patients.

Follow-Up Evaluation After EUS-GBD

After resolution of cholecystitis with EUS-GBD, there are 2 options for stent management. One option is routine follow-up peroral cholecystoscopy at 4 to 6 weeks after initial drainage to achieve complete stone clearance if stones have not already passed spontaneously. Simultaneously, an exchange of the LAMS for double pigtail plastic stents can be performed to maintain the fistula long-term. The technical success rate of this approach has been reported at 93.1%.[8] Fifty-six percent of patients had spontaneous stone passage,

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while the remaining patients required stone removal with stone-retrieval baskets and or laser lithotripsy.[8] Overall stone clearance was 88% after a mean of 1.25 cholecystoscopy sessions (SD, 0.46 sessions).

The second option of leaving the LAMS in permanently often is used in frail patients and in those who refuse a second procedure. In a study reporting the long-term outcomes (median follow-up period, 275 d) of EUS-GBD, delayed adverse events were low at 7.1% with a 3-year stent patency of 86%, making this a reasonable approach in select very-high-risk patients.[9]

Training

Although EUS-GBD has become mainstream, this procedure still is limited to centers of high volume and expertise in biliary disease and interventional EUS. Performing the procedure has an associated learning curve and requires advanced EUS training. Two recent publications have suggested that the minimum number of procedures to gain competency should be approximately 19 to 25 procedures.[28,29] In our institutions, we start with teaching the use of LAMS to drain pancreatic fluid collections (the Food and Drug Administration–approved indication) and achieving a level of comfort in this location before moving on to gallbladder drainage. In our institution, successful deployment of at least 10 LAMS in the setting of pancreatic fluid collections independently, then allows a trainee to proceed with performig EUS-GBD. Starting with gallbladders that are significantly distended with no intervening tissue is then the appropriate next target site to learn to use a LAMS. Instead of a specific number of cases, we observed several factors that influence the learning curve for these procedures, including prior experience, presence of prior training on models, and the individual learning curve of each trainee.

Future Directions

More data must be gathered on the outcomes and safety of EUS-GBD to allow Food and Drug Administration approval for LAMS or other devices to be used for this indication. With larger clinical experience, there are opportunities to standardize patient selection, procedure technique, and stent follow-up evaluation. Furthermore, more applications for EUS-GBD including a salvage maneuver for biliary drainage and removal of gallstones already are being performed. This begs the question of whether endoscopic management of cholecystitis and symptomatic gallstones could become mainstream treatment in the future. There are ongoing studies currently attempting to address this specific question and look forward to their outcomes. Although an enticing thought, we are still a long way from abandoning standard of care with cholecystectomy.

Conclusions

Endoscopic GBD is an established option for high-surgical-risk patients with acute cholecystitis. Determining which method of endoscopic drainage is most suitable requires consideration of comorbidities, the patient's anatomy (GB position, cystic duct characteristics, in-dwelling metal biliary stent), presence of ascites, potential future surgical candidacy, and available local expertise (endoscopic, radiographic, and surgical). ET-GBD should be prioritized for patients requiring ERCP for alternative reasons, those with large-volume ascites, and when needed as a temporizing measure. Conversely, EUS-GBD is preferred for patients who are poor candidates for repeat intervention, those with uncovered metal biliary stents, or tumors occluding the cystic duct and/or high-volume cholelithiasis that can be addressed using per-oral cholecystoscopy. LAMS can be left in place long term; however, in patients willing to undergo a second procedure, exchanging the LAMS for potentially less traumatic plastic stents often is performed at 4 to 6 weeks. EUS-GBD should be performed by those expert in advanced therapeutic EUS, and that essential training/mentorship is achieved before independent use. Ultimately, more randomized and prospective data are needed to compare ET-GBD and EUS-GBD outcomes, including cost-analysis studies.

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Conflicts of interest
These authors disclose the following: Shayan Irani is a consultant for Boston Scientific, ConMed, and GORE; and Uzma Siddiqui performs receives research support from Boston Scientific and Olympus, is a consultant and speaker for Boston Scientific, Cook, Medtronic, Olympus and ConMed. The remaining author discloses no conflicts.

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